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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,050	01/25/2006	Ji-Hyun Kim	Q90861	8300

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

VAKILI, ZOHREH

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/554,050	KIM ET AL.	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>January, 25, 2006</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 25, 2006 is acknowledged and entered.

Status of claims

Claims 1-5 are pending.

Claims 1-5 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. (US Patent No. 6589566 B2), in view of Spiegel (US 2004/0082657 A1), in view of

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Kao et al. (American Journal of Clinical Nutrition, Vol. 72, No. 5, 1232-1233), and further in view of Day et al. (US Patent No. 6706743 B2).

Ueda et al. in its invention relates to a theanine-containing composition which can be used for a food composition, a pharmaceutical composition, and the like, for suppressing and ameliorating various symptoms accompanying diminished homeostasis, such as obesity (see col. 1, lines 11-17). Ueda et al. teaches any of L-theanine, D-theanine and DL-theanine are usable, among which the L-form is preferred in the present invention, because it is approved as a food additive, and it is economically utilizable (see col. 3, lines 5-8). The content of the theanine in the composition is preferably from 0.00025 to 100 percent by weight, more preferably 0.005 to 100 percent by weight. The term "obesity" as used in the present invention refers to a form of obesity accompanied by complications due to over-accumulation of fat (see col. 4, lines 5-9). As for suppressing an effect for obesity, a satisfactory effect can be obtained when the theanine is preferably administered at 0.3 mg/kg a day or more, and as the amount of the administration is increased, its effect is further enhanced (see col. 4, lines 12-17).

Spiegel teaches in its invention a method and composition for suppressing the appetite of a human being using L-theanine. The L-theanine composition used as an appetite suppressant in accordance with the invention can be provided in solid form or liquid form and can be further combined with one or more inert ingredients or one or more additional active ingredients (see abstract). If L-theanine is used with an additional appetite suppressant is preferably not a stimulant such as caffeine,

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ephedrine, amphetamine or methamphetamine (see 0014). Spiegel further teaches additional active ingredients such as fat metabolizers including chromium picolinate, L-cysteine and L-carnitine (see 0015).

Kao et al. with the findings in their studies showed that intraperitoneal injection of epigallocatechin gallate (EGCG) caused acute body weight loss in male and female rats within 2-7 days of treatment. EGCG also significantly reduced or prevented an increase in body weight in lean and obese male and female rats. The loss in body weight was reversible when EGCG administration was stopped, animals regained the lost body weight. The weight-loss effect of EGCG in rats may have been due to a reduction in food intake. Male rats given EGCG orally consumed about 15 percent less food than did the control rats and lost 5 percent of their initial body weight. Male and female rats and male lean and obese rats injected intraperitoneally with EGCG consumed about 50-60 percent less food than did control rats. Studies have shown that oral consumption of green tea, EGCG, EGCG-containing green tea extract can lower serum and LDL cholesterol, increase HDL cholesterol, and lower serum glucose. On the basis of the in vivo effects of EGCG on body weight loss, body fat, serum lipid, nutrients, thermogenesis, and fat oxidation and of the in vitro effects of EGCG on fat cell functions, long term consumption of green tea may decrease the incidence of obesity and, perhaps, green tea components such as EGCG may be useful for treating obesity (see AJCN, vol. 72, No. 5, 1232-1233).

Day et al. teaches compounds that are Beta 3-adrenergic receptor agonists and, accordingly, have utility as, inter alia, hypoglycemic, and anti-obesity agents (see col. 1,

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lines 15-18). The compounds, pharmaceutical compositions, and combinations of the invention also reduce body weight or decrease weight gain when administered to mammal. The ability of the compounds to affect weight gain is due to activation of Beta 3-adrenergic receptors which stimulate the metabolism of adipose tissue (see col. 2, lines 12-17). Day et al. further teaches Beta Adrenergic agents have been generally classified into Beta₁, Beta₂, and Beta₃ receptor specific subtypes. Activation of Beta₃ receptors is known to stimulate lipolysis (e.g., the breakdown of adipose tissue triglycerides into glycerol and fatty acids) and metabolic rate (energy expenditure), thereby promoting the loss of fat mass. Accordingly, compounds that stimulate Beta₃ receptors are therefore useful as anti-obesity agents, and can be further used to increase the content of lean meat in edible animals (see col. 2, lines 24-32).

It would have been obvious to one skilled in the art to use the teachings of Ueda et al. for its theanine-containing composition that has suppressive effect and ameliorating effect on various diseases. For the purpose of suppressing and ameliorating symptoms accompanying diminished homeostasis, concretely for obesity suppression taken with Yoshida et al. teaching of a composition for suppressing the appetite of a human being comprising L-theanine combined with one or more inert ingredients or one or more additional active ingredients and combined with the teachings of Kao et al. regarding the findings of weight loss effect of epigallocatechin gallate (EGCG) in rats and further with teachings of Day et al. for introducing Beta 3-adrenergic receptor as an anti-obesity agent.

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Therefore, one having ordinary skill in the art at the time of invention was made would have been motivated to use the teachings of the prior arts cited above about a composition for weight loss comprising theanine along with rest of the other components.

In the absence of any criticality/unexpected results presently claimed invention is considered *prima facie* obvious over the prior arts for the reasons cited above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Zohreh Vakili

Patent Examiner
1614

September 16, 2006

Ardin H. Marschel 9/17/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER